Missouri Department of Health and Senior Services'

BUREAU OF NARCOTICS & DANGEROUS DRUGS

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New Controlled Substances Scheduled

The United States Drug Enforcement Administration has added two new substances to the list of controlled substances. Tapentadol is an opioid analgesic added to Schedule II. Vimpat™, generic name lacosamide is an anti-convulsive added to Schedule V.

Patients With Unwanted Medications

Medical practitioners with BNDD and DEA registrations destroy their unwanted controlled substances according to regulations, with witnesses to wastage or reverse distributors depending on the practice setting. The DEA is addressing how non-registrants such as patients can dispose of unwanted controlled substances in their homes.

- The DEA sought comments in the Federal Register on January 21, 2009, by publishing *"Disposal of Controlled Substances by Persons Not Registered With the Drug Enforcement Administration."*
- It seeks options for safe and responsible disposal of patient-owned medications;
- The comment period ended March 23, 2009;
- 158 comments were received nationwide;
- At this time, patients are not authorized to transfer possession of controlled substances. A change in the Controlled Substances Act of 1970 is required.
- Two bills are pending in the U.S. House of Representatives. House Resolution 1191 is by Rep. Inslee (WA) and House Resolution 1359 is by Rep. Stupack (MI).

Update on Status of Electronic Prescribing Rules

At this time, practitioners and pharmacies cannot transmit electronic prescriptions for controlled substances. Electronic and digital signatures are not allowed via computer transmission or fax. The DEA is in the process of promulgating a new rule. An update is provided below:

- The rule was initial published in the Federal Register on June 27, 2008;
- The comment period ended September 25, 2008;
- 230 comments were received nationwide;
- The DEA is preparing the final rule that may be out in the Fall of 2009;
- The process will include initial identification and verification of the prescriber;
- Two factor identification;
- Use of Health and Human Services Transmission Standards;
- No alteration of prescriptions during transmissions;
- Follow up reviews and verifications by prescribers of transmissions they have sent.

Online/Internet Pharmacies Not Legal at This Time

Effective April 13, 2009, the Controlled Substance Act was amended to add new provisions to prevent illegal drug distribution by internet. As of this date, 7-1-09, the DEA has not issued a registration to any online/internet pharmacies. At this time, only 5 applications are pending nationwide.

1. It is known as the Ryan Haight Online Pharmacy Consumer Protection Act;
2. It defines "online internet pharmacy";
3. Pharmacies must obtain a special modified DEA registration;
4. There are specific requirements for what must be posted on their homepage such as a list of all physicians they deal with;
5. In-patient physical exams are required;
6. The pharmacies must file monthly reports with the DEA.

Instructing Patients on Proper Medication Disposal

The DEA is currently reviewing rules for non-registrant patients to dispose of unwanted pharmaceuticals. In the meantime, how should patients properly dispose of their unwanted medications? Here are some basic points published by the Missouri Department of Health and Senior Services and the Missouri Department of Natural Resources:

1. Do Not Flush Medications
   This practice can harm bacteria that break down waste and then partially treated medications are released into nearby lakes and streams.

2. Solid Medications
   - Remove from the original container and place contents in a hard plastic container such as a plastic laundry detergent bottle;
   - Add a small amount of water to dissolve the medicine;
   - Add a thickening material such as cat litter, flour, salt, charcoal or coffee grounds;
   - Adding hot spices such as mustard or cayenne may deter people from ingesting;
   - Recap the container and seal with duct tape and place it in your trash just prior to pick-up.
3. Blister-Packaged Medications
   - Keep tablets in original packaging;
   - Wrap the pack with duct tape;
   - Place in hard plastic container as described above and place in trash.

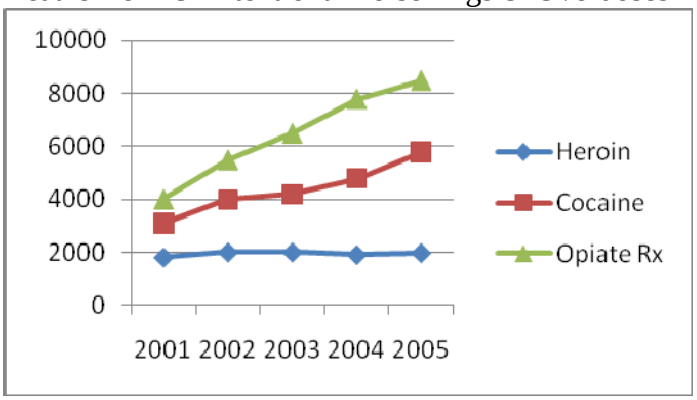
4. Liquid Medications
   - Remove from original container and dump into hard plastic container such as a laundry detergent bottle;
   - Add a thickening material such as salt, flour, cat litter, charcoal or coffee grounds;
   - Add hot spices to deter kids or animals from ingesting;
   - Seal container with duct tape and place it in trash just prior to pick up.

National Prescription Drug Threat Assessment

The National Drug Intelligence Center and Drug Enforcement Administration has published the 2009 drug threat assessment.

Diversion of controlled substances for non-medical abuse has increased consistently since 2003. The highest percentage of increases was for hydrocodone products (118%), morphine (111%) and methadone (109%).

Deaths from Unintentional Poisonings & Overdoses



In testimony before a Congressional Subcommittee on Criminal Justice and Drug Policy in 2006, Director Nora Volkow, M.D. of the National Institute on Drug Abuse stated:

The recent increase in the extent of prescription drug abuse in this country is quite likely the result of a confluence of factors such as significant increases in the numbers of prescriptions; increases in drug availability; aggressive marketing by drug manufacturers; and proliferation of internet pharmacies that dispense without proper prescriptions and surveillance. There is a greater social acceptability for medicating a growing number of ailments and this leads to misguided conclusions that their nonmedical abuse should be equally safe.

Midwest HIDTA: 2009 Drug Market Analysis

A HIDTA is an area deemed by the government to be a High Intensity Drug Trafficking Area. The Midwest HIDTA that includes Missouri released their 2009 analysis. Some Kansas City area law enforcement agencies report that abuse of controlled prescriptions drugs is one of the greatest drug threats in their jurisdictions and they are investigating increased overdoses, particularly among Caucasians ages 16 to 24.

Legislative Update

There were three bills that passed during this past session that directly impact the bureau and controlled substance laws in Missouri.

CCS HCS SB 296: This bill awaits signature on the governor's desk. This bill if enacted would provide limited controlled substance privileges to physicians' assistants who are under a supervision agreement. The physician assistant must meet training standards set by the law and receive a certificate from the state licensing board. The physician assistant may apply for controlled substance registrations from the state BNDD and then the federal DEA. The physician assistant would have to first obtain a consultation from the supervising physician, and then after receiving instructions each time, the physician assistant may carry out the instruction to issue a controlled substance prescription. There are limitations on the prescriptions and the prescriptions must document both the assistant's BNDD number and DEA number and identify the supervising physician.

SS SCS HSC HB 22: This is a budget bill that was signed by the governor and provides federal stimulus money to assist the state in implementing a pseudoephedrine tracking database. People illicitly manufacturing methamphetamine are "*smurfing*" their chemicals and jumping from pharmacy to pharmacy to purchase the maximum amount of pseudoephedrine in order to make meth. Section 195.017.13, RSMo requires all retail pharmacies dispensing pseudoephedrine to report their sales to a centralized database so that law enforcement may track sales. At this time the bureau is planning meetings with the pharmacy industry, law enforcement organizations and their respective associations so that rules may be promulgated to define how the reporting process and database will operate. Part of the process will include training for employees of pharmacies and law enforcement agencies.

CCS SCS HCS HB 5: This is a budget bill that was signed by the governor and provides federal stimulus money to assist the bureau in upgrading the BNDD registration database. At this time the bureau registers individual registrants such as physicians, dentists, veterinarians, pharmacies, researchers and other entities with controlled substance authority. The bureau issues 24 different registration types and has approximately 28,000 registrants. All of these registrants have independent statutory authority. During the past year the state has authorized a new authority for mid-level practitioners. These would be practitioners who receive some limited controlled substance authority through a collaborative practice agreement or a physician's supervision agreement. The mid-level practitioner's registration must be tied to the main physician and also the physician's registration must identify the mid-level practitioners they supervise. The bureau's database currently is not set up for these mid-level registrations for advance practice nurses and physicians' assistants so the bureau will have to upgrade their database before any new registrations can be issued to these mid-level practitioners.

State boards must promulgate rules for the mid-level practitioners and then the BNDD must also promulgate rules and provide an application and application process and prepare a database to issue the registrations. The state boards have already been meeting to promulgate rules for advanced practice nurses. The bill for physicians' assistants described above has not been signed by the governor at the time of this newsletter.

Mid-level practitioners should not submit any applications to the BNDD until they have first obtained their required certificate from their state licensing board and then completed the proper application from the BNDD.